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April 21, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 20204

Dear Sir or Madam:

This notification is being filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 343(r)(6), and in accordance with the requirements of 21 C.F.R.§ 101.93. Uniweal, Ltd., Room 803, Corn Yan Center, 3 Jupiter Street, North Point, Hong Kong, People's Republic of China, plans to market a dietary supplement bearing the following statements on the label and/or in the labeling:

Name of supplement: ONAPHON™

Dietary ingredients: White Peony Root (Bai-Shao)

Cassia (twig)

Ginger (root)

Jujube (Da-Zao) (fruit)

Licorice, Chinese (Gan-Zao) (root)

Structure/function statements:

1. This product helps to warm and soothe the stomach—This statement is the subject of Xiaojianzhong Mixture, which contains White Peony Root (Bai-Shao),

97S-0162

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Cassia (twig), Ginger (root), Jujube (Da-Zao) (fruit), and Licorice, Chinese (Gan-Zao) (root).

2. This product helps to regulate the function of the digestive system—This statement is the subject of Xiaojianzhong Mixture, which contains White Peony Root (Bai-Shao), Cassia (twig), Ginger (root), Jujube (Da-Zao) (fruit), and Licorice, Chinese (Gan-Zao) (root).

Summary of Substantiation:

The claims "helps to warm and soothe the stomach" and "helps to regulate the function of the digestive system" for Xiaojianzhong Mixture, and thereby ONAPHON™, are based on, and supported by, reference to authoritative scientific literature, and the existence of the previously notified/permitted claims for selected Xiaojianzhong Mixture ingredients.

The Pharmacopoeia of the People's Republic of China, which is approved by the Ministry of Public Health of the People's Republic of China, states that Xiaojianzhong Mixture is comprised of the above five dietary ingredients, and is produced through a specific manufacturing procedure (see attached).[1/] The Pharmacopoeia of the People's Republic of China states that the action of Xiaojianzhong Mixture is "to warm and invigorate the spleen and the stomach, and relieve pain," and that Xiaojianzhong Mixture is indicated for "deficiency-cold syndrome of the spleen and stomach marked by epigastric pain alleviated by warmth and pressing, acid regurgitation, anorexia and palpitation, as occurring in peptic ulcer."

Further, the Pharmacopoeia of the People's Republic of China states the following actions and indications for the component ingredients of Xiaojianzhong Mixture:

- Cassia (twig): Indications—epigastric pain with cold feeling, and gastro-intestinal neurosis with a feeling of masses of gas rushing up through the chest to the throat from the lower abdomen;

- Ginger (root): Action—to warm the stomach and arret vomiting; Indications—vomiting caused by cold in the stomach; and

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1/ THE PHARMACOPOEIA COMMISSION OF PRC, PHARMACOPEIA OF THE PEOPLE'S REPUBLIC OF CHINA (English ed. 1997, Chemical Industry Press) (1997).

- Licorice, Chinese (Gan-Zao) (root): Action—to reinforce function of the spleen; Indications—weakness of the spleen and the stomach marked by lassitude and weakness, and spasmodic pain in the epigastrium, abdomen, and limbs.

FDA has previously been notified of, and has permitted, claims similar to the proposed claims for certain of the Xiaojianzhong Mixture ingredients. Specifically, notified and permitted structure/function claims for ginger include the following:

- "a soothing herb for the stomach and may help maintain a calm stomach while traveling";[2/]
- "supports healthy digestive system";[3/]
- "eases the discomfort associated with travel and stimulates digestion to promote gastrointestinal comfort";[4/]
- "to help maintain calm stomach function";[5/]
- "to help stimulate digestion";[6/]
- "aids digestion";[7/]

2/ *Dietary Supplement Structure/Function Claims: Pharmavite*, F-D-C REP. ("THE TAN SHEET"), Dec. 7, 1998.

3/ *Dietary Supplement Structure/Function Claims: USA Nutritionals (Division of Action Labs)*, F-D-C REP. ("THE TAN SHEET"), Oct. 26, 1998.

4/ *Dietary Supplement Structure/Function Claims: Murdock Madaus Schwabe Professional Products*, F-D-C REP. ("THE TAN SHEET"), Oct. 12, 1998.

5/ *Dietary Supplement Structure/Function Claims: Naturade*, F-D-C REP. ("THE TAN SHEET"), Oct. 12, 1998.

6/ *Pharmanex Revising Goldenseal, Evening Primrose Oil, Cranberry Label Claims*, F-D-C REP. ("THE TAN SHEET"), July 20, 1998.

7/ *Sinomedical "Soften Blood Vessels," Improve Circulation Supplement Claims Filed*, F-

(continued...)

- "helps to stimulate digestive enzymes and increases production and secretion of bile from the liver and gall bladder...provides nutritional support for the digestive and circulatory systems";[8/] and

- "has been linked to beneficial compounds which warm and soothe the stomach."[9/]

In addition, there is a relevant, notified and permitted structure/function claim for licorice: "extensive worldwide use supports [licorice's] soothing benefits for the stomach, digestive tract, and as an antioxidant."[10/]

Therefore, the proposed claims "helps to warm and soothe the stomach" and "helps to regulate the function of the digestive system" are proper and supportable for Xiaojianzhong Mixture, and therefore ONAPHON™.

The undersigned certifies that the information presented and contained in this notification is complete and accurate, and that Uniweal, Ltd. has substantiation that each structure/function statement is truthful and not misleading.

Sincerely,

Stephen Paul Mahinka
Counsel for Uniweal, Ltd.

Attachments

7/(...continued)
D-C REP. ("THE TAN SHEET"), Dec. 15, 1997.

8/ *Dietary Supplement Structure/Function Claims: Ginger*, F-D-C REP. ("THE TAN SHEET"), May 11, 1998.

9/ *Amrion Rolling Out Natrix International's Advanced Botanics Line*, F-D-C REP. ("THE TAN SHEET"), April 29, 1996.

10/ *Supplement "Tumor Inhibition," "Virus Control," "Gingival Health" Claims Flagged by FDA*, F-D-C REP. ("THE TAN SHEET"), April 1, 1996.

PHARMACOPOEIA OF THE PEOPLE'S REPUBLIC OF CHINA

(English Edition 1997)
Volume I

Compiled by The Pharmacopoeia Commission of PRC

CHEMICAL INDUSTRY PRESS
BEIJING, CHINA

PHARMACOPOEIA OF THE PEOPLE'S REPUBLIC OF CHINA

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Volume I

This Pharmacopoeia is the English version edited from Pharmacopoeia of the People's Republic of China 1995 edition. The Chinese edition is approved by the Ministry of Public Health of the People's Republic of China to be effective from April 1, 1996, in accordance with the official document WYF (95) 77.

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Contents

MONOGRAPHS

PART I

Chinese Materia Medica, Oil, Fats, etc.

monia TS, then macerate 10 ml of chloroform for 30 minutes and ultrasonicate for 30 minutes, filter. Evaporate the filtrate to dryness, dissolve the residue in 1 ml methanol. Take 3～4 drops of the methanol solution into a 10 ml stoppered test tube. Add 0.5ml of chromotropic acid and 3 ml of sulfuric acid and heat the test tube on a water bath for 10 minutes, a deep purple colour appears.

(3) Add 15 ml of ethanol to 1 g of the reference drug of Radix Zanthoxyli, warm macerate for 30 minutes then ultra-sonicate for 30 minutes, filter. Evaporate the filtrate to dryness, dissolve the residue in 1 ml of ethanol and use it as the reference drug solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G as the coating substance and benzene-ethyl acetate-methanol-isopropanol-concentrated ammonia TS (20:5:3:1:0.12) as the mobile phase. Apply separately to the plate 2 μl of each of the test solution, the reference drug solution, and the reference solution used for assay. After developing in a chamber pre-equilibrated with mobile phase for 10 minutes and removal of the plate, dry it in air and examine under ultraviolet light (365 nm). A fluorescent spot in the chromatogram obtained from the test solution corresponds in colour and position to the spot in the chromatogram obtained from the solution of reference drug, and a light yellow fluorescent spot corresponds in colour and position to the spot in the chromatogram obtained from the reference solution used for assay.

(4) Dissolve ethoxychelerythrine CRS in methanol to produce a solution containing 1 mg per ml used as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G as the coating substance and toluene-ethyl acetate-methanol (25:2:0.1) as the mobile phase. Apply separately to the plate 2 μl of the reference solution, 2 μl of each of the solution of reference drug and test solution used in identification (3). After developing in a chamber pre-equilibrated with mobile phase for 10 minutes and removal of the plate, dry it in air, examine under ultra-violet light. A fluorescent spot in the chromatogram obtained from the test solution corresponds in colour and position to the spot in the chromatogram obtained from the reference drug, and orange-yellow fluorescent spot corresponds in colour and position to the spot in the chromatogram obtained from reference solution.

Assay To 1 g coarse powder, weighed accurately, in a Soxhlet's extractor, extract by heating under reflux until the reflux fluid becomes colourless. Concentrate the extract on a water bath to about 2 ml, transfer it into a 10 ml volumetric flask, add methanol to volume, mix well and use it as the test solution. Dissolve nitidine chloride CRS, weighed accurately, in methanol to produce a solution containing 0.5 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G containing sodium carboxymethyl cellulose as the coating substance and, weighed accurately, benzene-ethyl acetate-methanol-isopropanol-concentrated ammonia TS (20:5.3:1:0.12) as the mobile phase. Apply alternatively 4 μl of test solution, 1 μl and 4 μl of reference solution to the plate. After developing and removal of the plate, dry it in air, examine under ultra-violet light (365 nm), carry out the thin layer chromatography (thin layer chromatographic scanning method) (Apperdix VI B), scan the chromatogram at wavelength of λ_s = 300 nm, measure the integration values of absorbance for test solution and reference solution, calculate. It contains not less than 0.25% of nitidine chloride ($C_{21}H_{18}NO_3$), calculated on the dried basis.

Action To promote the flow of qi, relieve pain, to eliminate blood stasis, to promote blood circulation and dispel *wind*.

Indications Traumatic injury, rheumatic arthralgia, stomach-ache, teeth-ache, bitten by venomous snake, applied for burn caused by hot liquid or fire.

Usage and dosage 5～10 g; appropriate quantity for external use. Abrasive powder for application or simmer in water for washing the affected part of body.

Precaution Overdose is avoided, incompatible with food of sour flavour.

Storage Preserve in a dry place, protected from moisture and moth.

Ramulus Cinnamomi (桂枝, Guizhi)

Cassia Twig

Cassia Twig is the dired young stem of *Cinnamomum cassia* Presl (Fam. Lauraceae). The drug is collected in spring and summer, removed from leaf, dried in the sun or dried in the sun after sliced.

Description Long cylindrical, much- branched, 30～75 cm long, the thick end 0.3～1 cm in diameter. Externally brown to reddish-brown, with longitudinal lines, fine wrinkles, dotted leaf-scars, branch-scars and bud-scars, lenticels dotted or dotted elliptic. Texture hard and fragile, easily broken. Slices 2～4 mm thick, cut surface showing reddish-brown in bark, yellowish-white to pale yellowish-brown in wood, pith subsquare. Odour characteristic aromatic; taste, sweet and slightly pungent, relatively strong in bark.

Identification (1) Transverse section: Epidermis consisting of 1 layer of cells, non-glandular hairs unicellular, visible in young branches. Cork consisting of 3～5 layers of cells, the inner cells with thickened outer walls. Oil cells and stone cells scattered in cortex. Stone cells groups in pericycle interruptedly arranged in a ring, accompanied by fibre bundles. Secretory cells and fibres scattered in phloem. Cambium distinct. Xylem rays 1～2 cells wide, containing brown contents; vessels scattered singly or 2 to several aggregated; wood fibres with relatively thin walls, and differentiated uneasily from wood parenchymatous cells. In pith the walls of cells slightly thickened and lignified. Cells of rays containing fine needle crystals of calcium oxalate.

(2) To 0.5 g of the powder add 10 ml of ethanol, stopped tightly, macerate for 20 minutes with constant shaking, and filter, use the filtrate as the test solution. Dissolve cinnamic aldehyde CRS in ethanol to produce a solution containing 1 μl per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G as the coating substance and petroleum ether (boiling range 60～90℃)-ethyl acetate (85:15) as the mobile phase. Apply separately to the plate 10～15 μl of the test solution and 2 μl of the reference solution. After developing and removal of the plate, dry it in air, and spray with 0.1% 2, 4-dinitrophenyl-hydrazine solution. The orange-red spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Processing Eliminate foreign matter, soak briefly, wash clean, soften thoroughly, cut into thin slices, and dry in air.

Slices subrounded, elliptic or sections irregular, externally some with dotted lenticels and longitudinal lines, bark red-

dish brown. wood yellowish-white or pale yellowish-brown. pith subrounded or slightly square.

Action To induce perspiration, to warm the *channels* and stimulate menstrual discharge, to reinforce *yang*, to relieve palpitation, and to promote the descending of *qi*.

Indications Common cold; epigastric pain with cold feeling; amenorrhea due to *cold* in blood; arthralgia; edema; cardiac palpitation; gastro-intestinal neurosis with a feeling of masses of gas rushing up through the chest to the throat from the lower abdomen.

Usage and dosage 3～9 g.

Storage Preserve in a cool and dry place.

Ramulus et Folium Picrasmae (苦木, Kumu)

Indian Quassiawood

Indian Quassiawood is the dried stem and leaf of *Picrasma quassioides* (D. Don) Benn. (Fam. Simarubaceae). The drug is collected in summer and autumn, and dried.

Description Stems Cylindrical, varying in length, 0.5～2cm in diameter: externally greyish-green or brownish-green, with fine and dense longitudinal striations and numerous dotted lenticels; texture fragile, easily broken, fracture uneven, pale yellow, the young branches pale-coloured and large medullated. compound, leaves odd-pinnate easily falling off: leaflets ovate-elongated elliptical or ovato-lanceolate, subsessile, 4～16 cm long, 1.5～6 cm wide, apex acute, base oblique or slightly rounded, margins crenate, both surfaces usually green, somethimes the lower surface pale purplish-red, pubescent along the midrib. Odour, slight; taste, extremely bitter.

Identification (1) Powder: Yellowish-green. *Upper* epidermal cells of the leaf polygonal; stomata anomocytic, usually visible on the lower epidermal. Mesophyll cells frequently containing clusters of calcium oxalate. fibre bundles surrounded by parenchymatous cells containing clusters or prisms of calcium oxalate, forming crystal fibres.
(2) Macerate 1 g of the powder in 10 ml methanol over night, filter, evaporate the *filtrate* to dryness, dissolve the residue in 10 ml of methanol and use it as the test solution. Prepare a solution of Ramulus et Folium Picrasmæ reference drug in the same manner as the reference drug solution Carry out the method for thin layer chromatography (Appendix Ⅵ B) using silica gel G containing sodium carboxymethyl cellulose as the coating substance and a mixture of chloroform-methanol (85:15) as the mobile phase. Apply separately 10 μl of each of the above two solutions to the plate. After developing and removal of the plate, dry it in air, spray with modified potassium iodobismuthate TS. A spot in the chromatogram obtained from the test solution corresponds in colour and position to the spot in the chromatogram obtained from the reference drug solution.

Processing Eliminate foreign matter, wash the stems clean, soften thoroughly, cut into slices, and dry in the sun; spray the leaves with clean water, moisten briefly, cut into slivers, and *dry* in the sun.

Action To act against bacteria and relieve inflammation, to remove *damp*, and to counteract toxicity.

Indications Colds, acute tonsilitis, pharyngitis, colitis, bacillary dysentery, eczema, boils, venomous snake bite.

Usage and dosage 3～4.5 g of its branches or 1～3 g of its leaves; appropriate quantity for external use.

Storage Preserve in a dry place.

Ramulus Mori (桑枝, Sangzhi)

Mulberry Twig

Mulberry Twig is the dried young branch of *Morus alba* L. (Fam. Moraceae). The drug is collected at the end of spring and the beginning of summer, removed from leaf, and dried in the sun, or cut into slice while fresh, and dried in the sun.

Description Long cylindrical, branched occasionally, varying in length, 0.5～1.5 cm in diameter. Externally greyish-yellow or yellowish-brown, with numerous yellowish-brown dotted lenticels and fine longitudinal striations, and with greyish-white slightly semiorbicular leaf scars and yellowish-brown axillary buds. Texture hard and tenacious, uneasily broken, fracture fibrous. Slices 0.2～0.5 cm thick, bark slightly thin, wood yellowish-white, medullary rays radiate, pith white or yellowish-white. Odour, slight; taste, weak.

Identification Powder: Pale greyish-yellow. Fibres numerous, scattered singly or in bundles, pale yellow or colourless, slightly sinuous, 10～30 μm in diameter, walls thickened, 5～15 μm, pit-canals indistinct, lumina small. Stone cells pale yellow, subrounded or subsquare, 15～40 μm in diameter, walls thickened, 5～20 μm, lumina small. Sclerenchymatous cells grouped or scattered singly, similar to the stone cell in the shape and size, lumina containing 1～2 prisms of calcium oxalate, square, rhombic, polyhedral or biconelike, 5～20 μm in diameter.

Extractives Carry out the hot extraction method as described under the determination of ethanol-soluble extractives (Appendix Ⅹ A), using ethanol as the solvent, not less than 3.0%.

Processing *Ramulus Mori* Wash the whole ones clean and soften thoroughly, cut into thick slices, and dry in the sun.

Ramulus Mori (Stir-fried) Stir-fry the slices of Ramulus Mori as described under the method for simple stir-frying (Appendix Ⅱ D) to a yellowish colour.

Action To relieve rheumatic arthralgia.

Indications Aching and numbness of joints, particularly of the shoulders and arms.

Usage and dosage 9～15 g.

Storage Preserve in a dry place.

Ramulus Uncariae cum Uncis (钩藤, Gouteng)

Gambir Plant

Gambir Plant is the dried hook-bearing stem branch of *Uncaria rhynchophylla* (Miq.) Jacks., *Uncaria macrophylla* Wall., *Uncaria hirsuta*

the stomach; spitting of blood, epistaxis or abnormal uterine bleeding due to *deficiency of yang*, to keep the blood circulating within the vessels.

Usage and dosage 3~9 g.

Storage Preserve in a cool and dry place, protected from moth.

Preparation Extractum Zingiberis Liquidum.

Rhizoma Zingiberis Preparata (炮姜, Paojiang)

Prepared Dried Ginger

Prepared Dried Ginger is prepared from the Rhizoma Zingiberis.

Procedure Scald the clean dried Ginger with sand (Appendix II D) until inflated and brown externally.

Description Irregular inflated pieces with fingered branched. Externally brownish black or brown. Texture light and loose, fracture brownish black at the margin, brownish-yellow in the inner part, fine granular, vascular bundles scattered. Odour, aromatic and characteristic; taste, slight pungent.

Identification Powder: Brown. Starch granules abundant, ovoid, ellipsoid, detoid-ovoid, subrounded or irregular, 5~40μm in diameter, hilum pointed in the smaller end and cleft-like as well, sometimes striations visible, gelatinised masses visible occasionally. Oil cells and resin cells scattered in parenchyma, containing pale yellow oil drops or dark reddish brown contents. Fibres in bundles or scattered, blant-acute at the end, few branched, sometimes sinuated on one side, 15~40 μm in diameter, walls thickened slightly, nonlignified, with fine oblique pits and thin transverse septa usually visible. Vessels mostly scalariform reticulate or spiral, occasionally annular 15 vessels as well sometimes, beside the vessels or fibres with tubular cells containing dark reddish brown contents visible, 12~20 μm in diameter.

Total ash Not more than 7.0% (Appendix II K).

Action To reinforce *yang* and dispel cold, to arrest bleeding by reinforce meridians.

Indications Asthenia-cold of *spleen* and stomach, abdomenache, vomating and diarrhea, haematemesis, epistaxis, uterine bleeding, bleeding due to *yang-deficiency*.

Usage and dosage, Storage As described under Rhizoma Zingiberis.

Rhizoma Zingiberis Recens (生姜, Shengjiang)

Fresh Ginger

Fresh Ginger is the fresh rhizome of *Zingiber officinale* (Willd.) Rosc. (Fam. Zingiberaceae). The drug is collected in autumn and winter, removed from fibrous root and soil.

Description In irregular pieces, slightly compressed, with finger-like branches, 4~18 cm long, 1~3 cm thick. Externally yellowish-brown or greyish-brown, ringed, the top of each branch exhibiting a stem scar or buds. Texture fragile, easily broken, fracture pale yellow, with a well-marked endodermis ring and scattered vascular bundles. Odour, aromatic and characteristic; taste, pungent.

Processing *Rhizoma Zingiberis Recens* Eliminate foreign matter, wash clean and cut into thick slices before use.

Peel of Rhizoma Zingiberis Recens Scrape the outer peel of clean Rhizoma Zingiberis Recens.

Action To induce perspiration and dispel *cold*, to warm the stomach and arrest vomiting, and to resolve *phlegm* and relieve cough.

Indications Common cold; vomiting caused by *cold* in the stomach; cough with expectoration of whitish thin spurum.

Usage and dosage 3~9 g.

Storage preserve in a cool, dry place, or embed in wet sand, protected from freezing.

Sargassum (海藻, Haizao)

Seaweed

Seaweed is the dried alga of *Sargassum pallidum* (Turn.) C. Ag. or *Sargassum fusiforme* (Harv.) Setch. (Fam. Sargassaceae). The former is commonly known as "Daychaizao" and the latter is known as "Xiaoyehaizao". The drug is collected in summer and autumn, removed from foreign matter, washed clean, and dried in the sun.

Description *Daychaizao* Crumpled and rolled, blackish-brown, some showing white frost-like powder, 30~60 cm long, the stem-like stipe cylindrical, with conical protrudings. Main branchings dichotomous, lateral branchings giving off from the axils of blades bearing on main branchings, with short spiny protrudings. The blades of primary segments lanceolate or obovate, 5~7 cm long, about 1 cm wide, margin entire or dentate. The blades of secondary segments slat-shaped or lanceolate, with small branchings bearing slat-shaped segments in the axils of blades. Air bladders blackish-brown, spheroidal or ovoid, some with stalks, apex obtuse-rounded, sometimes mucronate. Texture fragile, soft when moistened, swollen, fleshy and lubricant on soaking in water. Odour, seafood-like; taste, slightly salty.

Xiaoyehaizao Slightly small, 15~40 cm long, lateral branchings alternate, without spiny protrudings, blades slat-shaped or spatulate, apex slightly swollen, hollowed, air bladders axillary, fusiform or spheroidal, with relatively long stalks. Texture relatively hard.

Identification Macerate 1 g of the small pieces in 20 ml of water for several hours and filter. Evaporate the filtrate to about 3~5 ml, add 3 drops of ferric chloride TS; a brown precipitate is produced.

Processing Eliminate foreign matter, wash clean, dry in the air briefly, cut into sections, and dry in the sun.

Action To soften indurated mass, to eliminte *phlegm* and dissipate nodulation, and to induce diuresis.

Indications Goiter, scrofula, swelling and pain of the testis; edema.

Usage and dosage 6~12 g.

Precaution Incompatible with Radix Glycyrrhizae.

Processing Soften thoroughly, cut into thin slices, and dry. Break to pieces before use.

Action Replenish vital essence, promote blood circulation and relieve collapse. To reinforce *qi* and to stanch bleeding.

Indications Collapse tendency due to asthenia, cool limbs and weak pulse. *Qi* cannot control blood, uterine bleeding, cardiac failure and cardiogenic shock.

Usage and dosage 3～9 g.

Precaution Incompatible with Rhizoma et Radix Veratri.

Storage Preserve in well closed containers, stored in a cool and dry place, protected from moth.

Radix Glehniae (北沙参, Beishashen)

Coastal Glehnia Root

Coastal Glehnia Root is the dried root of *Glehnia littoralis* Fr. Schmidt ex Miq. (Fam. Umbelliferae). The drug is collected in summer and autumn, removed from rootlet, washed clean, dried slightly in the air, treated with boiling water, peeled and dried, or dried immediately directly after washing.

Description Slenderly cylindrical, branching occasionally, 15～45 cm long, 0.4～1.2 cm in diameter. Externally yellowish-white, slightly rough, occasionally with patches of cork adhering, or yellowish-brown when unpeeled, finely wrinkled longitudinally, and with brownish-yellow spotted rootlet scars. Top usually with yellowish-brown remains of rhizome. The upper part somewhat thin, the middle part relatively thick, and the lower part tapering. Texture fragile, easily broken, fracture yellowish-white in bark and yellow in wood. Odour, characteristic; taste, sweetish.

Identification Transverse section: Cortex of several layers of parenchymatous cells, scattered with secretory canals. Cork visible when unpeeled. Phloem broad, rays distinct, sieve tube groups collapsed in the outer part and appearing as a narrow band; secretory canals scattered, 20～65 μm in diameter, containing yellow-brown secretion, surrounded by 5～8 secretory cells. Cambium in a ring. Xylem rays 2～5 cells wide; most vessels arranged in V-shape; parenchymatous cells containing gelatinized starch granules.

Processing Remove remains of stems and foreign matter, soften slightly, cut into sections, and dry.

Action To replenish *yin* of the *lung* and stomach, remove *heat* from the *lung*, and promote fluid secretion.

Indications Dry cough caused by *heat* in the *lung*; bloody sputum in phthisis; thirst in febrile diseases.

Usage and dosage 4.5～9 g.

Precaution Incompatible with Rhizoma et Radix Veratri.

Storage Preserve in a ventilated and dry place, protected from moth.

Radix Glycyrrhizae (甘草, Gancao)

Liquorice Root

Liquorice Root is the dried root and rhizome of *Glycyrrhiza uralensis* Fisch, *Glycyrrhiza inflata* Bat. or *Glycyrrhiza glabra* L. (Fam. Leguminosae). The drug is collected in spring and autumn, removed from rootlet, and dried in the sun.

Description *Root of Glycyrrhiza uralensis* Roots cylindrical, 2～100 cm long, 0.6～3.5 cm in diameter. The outer bark loose or tight. Externally reddish-brown or greyish-brown, obviously longitudinally wrinkled, furrowed, lenticellate, and with sparse rootlet scars. Texture compact, fracture slightly fibrous, yellowish-white, starchy, cambium ring distinct, rays radiate, some with clefts. Rhizomes cylindrical, externally with bud scars, pith present in the centre of fracture. Odour, slight; taste, sweet and characteristic.

Root of Glycyrrhiza inflata Roots and rhizomes woody and stout, some branched, the out bark rough, mostly greyish-brown. Texture compact, more lignified fibres and less starchy. Rhizomes with more and large adventitious buds.

Root of Glycyrrhiza glabra Texture of root and rhizomes relatively compact, some branched, the outer bark not rough, mostly greyish-brown, lenticels small and indistinct.

Identification (1) Transverse section: Cork consisting of several layers of brown cells. Cortex relatively narrow. Phloem rays broad, mostly curved, frequently with clefts; most phloem fibres in bundles, unlignified or slightly lignified, surrounded by parenchymatous cells containing prisms of calcium oxalate; sieve tube tissue often pressed to be collapsed. Fascicular cambium distinct. Xylem rays 3～5 cells wide; vessels frequent, up to 160 μm in diameter; xylem fibres in boundles, surrounded by parenchymatous cells containing prisms of calcium oxalate. Roots without pith at the centre; rhizomes possessing pith at the centre.

Powder: Brownish-yellow. Fibres in bundles, 8～14 μm in diameter, thick-walled, slightly lignified, surrounded by parenchymatous cells containing prisms of calcium oxalate, forming crystal fibres. Prisms of calcium oxalate frequent. Bordered pitted vessels large, reticulated vessels rare. Cork cells reddish-brown, polygonal, slightly lignified.

(2) To 1 g of the powder add 40 ml of ether, heat under reflux on a water bath for 1 hour, filter. Heat the residue under reflux in 30 ml of methanol on a water bath for 1 hour and filter. Evaporate the filtrate to dryness and dissolve the residue in 40 ml of water. Extract the aqueous solution with 3 quantities, each of 20 ml, of *n*-butanol. Combine the *n*-butanol solution, wash with water for 3 times and evaporate on a water bath to dryness, dissolve the residue in 5 ml of methanol as the test solution. Prepare a solution of Radix Glycyrrhizae reference drug in the same manner as the reference drug solution. Dissolve ammonium glycyrrhizate CRS in methanol to produce a solution containing 2 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G containing 1% solution of sodium hydroxide as the coating substance and ethyl acetate-methanol-glacial acetic acid-water (30:2:2:4) as the mobile phase. Apply separately to the plate 1～2 μl of each of

the three solutions. After developing and removal of the plate, dry it in air. Spray with 10% solution of sulfuric acid in ethanol. Heat at 105℃ to visualize clearly, and examine under ultra-violet light (365 nm). The fluorescent spot in the chromatogram obtained with test solution corresponds in position and colour to the spot obtained with the reference drug solution; the orange-yellow fluorescent spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Water Carry out the method for Determination of water (Appendix Ⅸ H, method 1), not more than 12.0%.

Total ash Not more than 7.0% (Appendix Ⅸ K).

Acid-insoluble ash Not more than 2.0% (Appendix Ⅸ K).

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into thick slices and dry.

Action To reinforce the function of the *spleen* and replenish *qi*, to remove *heat* and counteract toxicity, to dispel *phlegm* and relieve cough, to alleviate spasmodic pain, and to moderate drug actions.
Radix Glycyrrhizae (processed with honey) To reinforce the function of the *spleen* and replenish *qi*, and to restore the normal cardiac rhythm.

Indications Weakness of the *spleen* and the *stomach* marked by lassitude and weakness; cardiac palpitation and shortness of breath; cough with much *phlegm*; spasmodic pain in the epigastrium, abdomen and limbs; carbuncles and sores. It is often used for reducing the toxic or drastic actions of other drugs.
Radix Glycyrrhizae (processed with honey) Weakness of the *spleen* and the *stomach* with lassitude and lack of strength; arrhythmia.

Usage and dosage 1.5～9 g.

Precaution Incompatible with Radix Euphorbiae Pekinensis, Flos Genkwa and Radix Kansui.

Storage Preserve in a ventilated and dry place, protected from moth.

Preparation Liquorice Extract.

Radix Glycyrrhizae Preparata (炙甘草, Zhigancao)

Prepared Liquorice Root

The drug is the processed Radix Glycyrrhizae.

procedure Stir-fry the slices of Radix Glycyrrhize as described under the method for stir-frying with honey (Appendix Ⅱ D) until it becomes yellow to deep yellow and not stichy to the fingers, take out and cool in the air.

Description Occurring in subrounded or elliptical slices, externally reddish-brown or greyish-brown, slightly lustrous, cut surface yellow to deep yellow, cambium ring distinct, rays radiate. Texture slightly stichy. Odour, with agreeable burnt smelling; taste, sweet.

Identification Carry out the method as described under Identification test (2) in the monograph of Radix glycyrrhizae, it shows the same result.

Water Carry out the method for Determination of water (Appendix Ⅸ H, method 1). Not more than 10.0%.

Total ash Not more than 5.0% (Appendix Ⅸ K).

Acid-insoluble ash Not more than 1.0% (Appendix Ⅸ K).

Action To invigorate the function of *spleen* and stomach, to reinforce *qi* and promote blood circulation.

Indications Deficiency of *spleen* and stomach, lassitude, palpitation, arrhythmia.

Usage and dosage As described under Radix Glycyrrhizae.

Precaution As described under Radix Glycyrrhizae.

Radix Hedysari (红芪, Hongqi)

Manyinflorescenced Sweetvetch Root

Manyinflorescenced Sweetvetch Root is the dried root of *Hedysarum polybotrys* Hand.-Mazz. (Fam. Leguminosae). The drug is collected in spring and autumn, removed from rootlet and root stock, and dried in the sun.

Description Cylindrical, few-branched, upper end slightly thick, 10～50 cm long, 0.6～2 cm in diameter. Externally reddish-brown of grey tint, with longitudinal wrinkles, transversely elongated lenticels and a few rootlet scars, outer layer easily stripped off, the exposed layer yellowish. Texture hard and tough, fracture fibrous and starchy, yellowish-white in bark and yellowish-brown in wood, rays radial, cambium ring brownish. Odour slight; taste sweetish, slightly bean-like on chewing.

Identification Transverse section: Cork consisting of 6～8 layers of cells. Cortex narrow, with 2～4 layers of collenchymatous cells at the outside. Phloem broader, cleft outside, fibres in bundles scattered, with thickened walls, slightly lignified; phloem rays often curved outside. Cambium in a ring. Vessels in xylem singly scattered or 2～3 grouped, surrounded by wood fibres. Fibre bundles surrounded by parenchymatous cells containing prisms of calcium oxalate.
Powder: Yellowish-brown. Fibres in bundles, 5～22 μm in diameter, with thickened walls, slightly lignified, surrounded by a sheath of parenchymatous cells containing calcium oxalate prisms, forming crystal fibres, the walls of crystal cells unevenly thickened. Prisms of calcium oxalate 7～14 μm in diameter, up to 22 μm long. Bordered pitted vessels up to 145 μm in diameter. Starch granules simple or compound, subrounded or ovoid-rounded, 2～19 μm in diameter; compound of 2～8 components.

Extractives Carry out the method for Determination of ethanol-soluble extractives (Appendix Ⅹ A, the hot extraction method), using 45% ethanol as the solvent, not less than 30.0%.

Processing *Radix Hedysari* Eliminate foreign matter, grade according to size, wash clean, soften thoroughly, cut into thick slices, and dry.

Action To reinforce *qi* and strengthen the superficial resistance, to cause diuresis, and to promote the drainage of pus and the growth of new tissue.

Indications *Deficiency of qi* with lack of strength, anorexia and loose stools; sinking of the *spleen qi* marked by protracted diarrhea and prolapse of the rectum; hematochezia and abnormal uterine bleeding; spontaneous sweating due to weakened superficial resistance; edema due to *deficiency of qi*; abscess or boil difficult to burst; anemia; diabetes mellitus; albuminuria in chronic nephritis.

Usage and dosage 9～30 g.

PART II

Traditional Chinese Patent Medicines and Simple Preparations

hexane-ethyl acetate (8:2) as the mobile phase. Apply separately to the plate 5 μl of the test solution obtained under Identification test (2), and 2 μl of the reference drug solution. After developing and removal of the plate, dry it in air, spray with sulfuric acid. The black spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference drug solution.

Other requirements Comply with the general requirements for pills (Appendix I A).

Action To dispel *wind*, arrest convulsions, resolve *phlegm* and remove the retention of undigested food.

Indications Colds with indigestion in children, marked by fever, nasal obstruction, cough with much *phlegm*, vomiting, diarrhea, and even convulsion.

Usage and dosage 1 pill, 2~3 times a day.

Specification 1.5 g per pill.

Storage Preserve in tightly closed containers.

Xiaohuoluo Wan
(小活络丸)

Xiaohuoluo Pills

Ingredients Arisaema cum Bile 180 g; Radix Aconiti Preparata 180 g; Radix Aconiti Kusnezoffii Preparata 180 g; Lumbricus 180 g; Olibanum (processed) 66 g; Myrrha (processed) 66 g.

Preparation Pulverize the above six ingredients to fine powder and mix well. To each 100 g of the powder add 90 g of refined honey to make big honeyed pills.

Description Blackish-brown to black big honeyed pills; stinking; taste, bitter.

Identification Microscopical: Irregular masses colourless or yellow, plenty of minute granules diffused on the surface around, dissolved on long standing. Irregular masses pale yellow, translucent, with oil droplets, which turn brown on heating revealing square crystals of calcium oxalate. Stone cells rectangular or subsquare, with slightly thickened walls. Needle Crystals of calcium oxalate in bundles or scattered, 20~90 μm long.

Requirements Comply with the general requirements (Appendix I A).

Action To relieve rheumatic conditions and remove obstruction from the *collateral channels*.

Indications Rheumatic or rheumatoid arthritis with joint soreness and muscle contracture.

Usage and dosage 1 pill, 2 times a day, to be taken with wine or warm boiled water.

Contraindications Contraindicated in pregnancy.

Specification 3 g per pill.

Storage In tightly closed containers.

Xiaojianzhong Heji
(小建中合剂)

Xiaojianzhong Mixture

Ingredients Ramulus Cinnamomi 111 g; Radix Paeoniae Alba 222 g; Radix Glycyrrhizae (processed with honey) 74 g; Rhizoma Zingiberis Recens 111 g; Fructus Jujubae 111 g.

Procedure Distil volatile oil from Ramulus Cinnamomi and collect the aqueous solution after distillation in another container. Decoct the residue, Radix Glycyrrhizae and Fructus Jujubae with water 2 times, 2 hours for each time, combine the decoctions and filter. Combine the filtrate and the above aqueous solution and concentrate to about 560 ml. Macerate Radix Paeoniae Alba and Rhizoma Zingiberis Recens for 24 hours, using 50% ethanol as solvent, then carry out the method for percolation described under liquid extract and extract (Appendix I O). Collect the percolate, recover ethanol and mix with the above concentrated decoction. Allow it to stand, and filter. Add 370 g of maltose and concentrate to about 1000 ml. To the solution add 3 g of sodium benzoate and the volatile oil of Ramulus Cinnamomi, make up the volume to 1000 ml and stir well.

Description A brownish-yellow liquid; odour, slightly aromatic; taste, sweet and slightly pungent.

Identification (1) Extract 20 ml with 3 quantities, each of 15 ml, of ether with shaking. Combine the ether extracts, evaporate to dryness, and dissolve the residue in 0.5 ml of ethyl acetate as the test solution. Dissolve cinnamaldehyde CRS in ethanol to produce a solution containing about 1 μl per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G containing carboxymethyl-cellulose sodium as the coating substance and petroleum ether (60 ~ 90℃)-ethyl acetate (17:3) as the mobile phase. Apply separately to the plate 10 μl of the test solution and 1~2 μl of the reference solution. After developing and removal of the plate, dry it in air. Spray with a solution of dinitrophenylhydrazine in ethanol TS. The spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

(2) To the aqueous solution, extracted with ether, as described under Identification test (1), extract with 2 quantities, each of 15 ml, of *n*-butanol, combine the *n*-butanol extracts, wash with 10 ml of water. Discard the aqueous solution, evaporate the *n*-butanol extracts to dryness, and dissolve the residue in 1 ml of methanol as the test solution. Dissolve paeoniflorin CRS in methanol to produce a solution containing about 2 mg of per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G containing carboxylmethyl-cellulose sodium as the coating substance and chloroform-ethyl acetate-methanol-concentrated ammonia TS (8:1:4:1) as the mobile phase. Apply separately to the plate 2~3 μl of each of the two solutions. After developing and removal of the plate, dry it in air. Spray with a 5% solution of vanillin in sulphuric acid and heat under a current of hot air to visualize clearly. The spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

(3) To 0.5 g of Radix Glycyrrhizae reference drug add 10 ml of water, heat under reflux for 30 minutes, and filter. Treat the filtrate in the same manner as described under

Identification(2) as the reference drug solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G prepared with 1% sodium hydroxide solution and ethyl acetate-formic acid-glacial acetic acid-water(15:1:1:2)as the mobile phase. Apply separately to the plate 1—2 μl of each of the test solution obtained under Identification test(2)and the reference drug solution. After developing and removal of the plate, dry it in air. Spray with a 10% solution of sulphuric acid in ethanol and heat at 105℃ to visualize clearly. Examine under ultra-violet light (365nm). The fluorescent spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference drug solution.

Relative density Not less than 1.10 (Appendix VI A).

Other requirements Complies with the general requirements for mixtures (Appendix I J).

Action To warm and invigorate the *spleen* and the stomach, and relieve pain.

Indications *Deficiency-cold* syndrome of the *spleen* and the stomach marked by epigastric pain alleviated by warmth and pressing, acid regurgitation, anorexia and palpitation, as occurring in peptic ulcer.

Usage and dosage 20～30 ml, 3 times a day, shake before use.

Storage Preserve in tightly closed containers, protected from light.

Xiaojin Wan
(小金丸)

Xiaojin Pills

Ingredients Moschus 30 g; Semen Momordicae (removed from shell and oil) 150 g; Radix Aconiti Kusnezoffii Praparata 150 g; Resina Liquidamberis 150 g; Olibanum (processed) 75 g; Myrrha (processed) 75 g; Faeces Trogopterori (stir-fried with vinegar) 150 g; Radix Angelicae Sinensis (stir-fried with wine) 75 g; Lumbricus 150 g; Chinese Ink Cake 12 g.

Procedure Pulverize the above ingredients, except Moschus, to fine powder. Triturate Moschus with the above powder and sift. To each 100 g of the powder add 25 g of starch, mix well to make pills with the dilute paste, prepared from 5 g of starch, and dry at a lower temperature.

Description Blackish-brown pasted pills; odour, aromatic, taste, slightly bitter.

Identification Microscopical: Stone cells rectangular or subsquare, with slightly thickened walls. Cells of cotyledon rectangular or polygonal, containing aleurone grains and pieces of fatty oils. Parenchymatous cells fusiform, with slightly thickened walls and very fine oblique crisscross striations. Amorphous masses pale yellowish-brown, embedded with small square crystals. Muscle fibres layered, colourless, yellowish or brownish, sinuous, sometimes vertically crisscross arranged.

Other requirements Comply with the general requirements for pills (Appendix I A), except the disintegration test.

Action To dissolve lumps and cause subsidence of swelling, and to remove *blood stasis* and relieve pain.

Indications Genital phlegmon at the early stage with swelling and pain but no discoloration of the skin; multiple abscesses; goitre, scrofula, breast carcinoma, breast.

Usage and dosage 2—5 pills, 2 times a day, after break; appropriate reduction of the dosage for children.

Precaution Contraindicated in pregnancy.

Specification 0.6 g per pill.

Storage Preserve in tightly closed containers.

Xiaokechuan Tangjiang
(消咳喘糖浆)

Xiaokechuan Syrup

Xiaokechuan Syrup is prepared from Folium Rhododendri Daurici.

Procedure To 200 g of Folium Rhododendri Daurici add about 950 ml of 40% ethanol, close well, macerate at 40℃ for 7 days, stir 2—3 times a day, filter and squeeze the residue. Combine the squeezed solution and the filtrate, allow to stand, filter, add 350 g of sucrose to the filtrate to dissolve, add 40% ethanol to 1000 ml, stir well, allow to stand, and filter.

Description A reddish-brown liquid; odour, aromatic; taste, sweet, pungent and bitter.

Identification Extract 25 ml of the syrup with 2 quantities, 15 ml of each, of ether, combine the extract and evaporate to dryness. Add 40% ethanol for three times, 10 ml each, to dissolve the residue by heating on a water bath, filter while hot, combine the filtrate, evaporate the ethanol on a water bath. Extract the remaining water solution with 2 quantities, 15 ml of each, of ether, combine the ether extract, evaporate to dryness, dissolve the residue in 1 ml of chloroform as the test solution. To 5 g of Folium Rhododendri Daurici reference drug, add 50 ml of ether, ultrasonicate for 15 minutes, filter and evaporate the filtrate to dryness. Dissolve the residue in 30 ml of 40% ethanol, and prepare the reference drug solution in the same manner of the test solution preparation. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G as the coating substance and hexane-ethyl acetate-methanol (5:5:0.2)as the mobile phase. Apply separately to the plate 5 μl of the two solutions. After developing and removal of the plate, dry it in air, and examine under ultra-violet light (365nm). The fluorescent spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Ethanol content 20%—28%(Appendix IX M).

Relative density Not less than 1.08(Appendix VI A).

Other requirements Complies with the general requirements for syrups(Appendix I H).

Assay *Standard preparation* Weigh accurately 30 mg of rutin CRS, previously dried in vaccum to constant weight at 120℃, in a 100 ml volumetric flask, dissolve in a quantity of 60% ethanol, dilute to volume, and mix well. Measure accurately 10 ml of the solution to a 50 ml volumetric flask, dilute with 60% ethanol to volume, mix well as the standard solution(containing 60 μg of anhyddrous rutin per ml).

Preparation of standard curve measure accurately 0.0, 0.5, 1.0, 2.0, 3.0, 4.0 and 5.0 ml of the standard solution

Appendix XVI
Explanation of Chinese Medical Terms

The following terms are used in traditional Chinese medicine and adopted in the individual monographs of crude drugs, dosage forms and Chinese patent medicines under the headings of "Action", "Indication", "Usage and dosage" and "Precaution".

blood stasis Local stoppage or slowness of the blood flow or general sluggishness of blood circulation. It is usually manifested by pricking or stabbing pain fixed in position and with tenderness, amenorrhea or diminished menstrual flow with discharge of dark blood clots, mass formation in the abdomen, dry scaly skin, purpura or ecchymosis, cyanosis of the tongue or purple dots or spots on the tongue. According to modern researches, blood stasis in traditional Chinese medicine may include the following pathological changes: ischemia, congestion, thrombosis, bleeding due to microcirculatory disturbance, inflammatory exudation, atrophy and hyperplasia, and even the formation of tumour. The principal treatment is to remove or eliminate blood stasis by activating or promoting the blood circulation.

channels and collaterals According to the theory of channels (or meridians), there exists in the human body a system of channels through which qi (vital energy) and blood circulate, and by which the internal organs are connected with the superficial organs and tissues. There are 12 regular channels (main meridians) and 8 extra channels. Collaterals are the branches of the channels. There are 15 main collaterals with subdivision of numerous secondary and tertiary collaterals. Many morbid conditions may be caused by obstruction of the collateral channels, e.g. obstruction by wind, cold and damp is believed be a common cause of arthritis with joint pain and limitation in motion, hemiplegia with numbness of the limbs is also due to obstruction in the collateral channels. Thus, removal of the obstructions from the affected collaterals is the main treatment of these morbid conditions.

cold (1) An exogenous pathogenic factor that brings on the syndrome marked by chilliness, mild fever, headache, general aching, but no sweating, when it invades the superficial portion of the body (also called **wind-cold** syndrome), or the syndrome marked by vomiting, abdominal pain, diarrhea, borborygmi and even shivering chills and syncope when it directly attacks the stomach and the intestines.
(2) An endogenous pathogenic factor due to deficiency of **yang** (vital function) that causes various morbid conditions marked by intolerance of cold, cold extremities, pale tongue with whitish coating, weak and slow pulse, also called **deficiency-cold**. Besides the above common features, each morbid condition caused by deficiency-cold has its own characteristics, such as relief by warmth in epigastric or abdominal pain of deficiency-cold type, difficulty in exhalation and expectoration of whitish thin sputum in dyspnea of deficiency-cold type, thin whitish discharge and discharge of pale red blood in leukorrhea and excessive menstrual flow of deficiency-cold type respectively. The principal treatment of the syndromes or morbid conditions caused by cold is to dispel cold. In case of deficiency-cold, drugs to warm the internal organs by invigorating the vital function (**yang**) are also necessary, but most of the drugs to dispel cold have warming effects.

cold-damp (1) Cold and damp in combination as a pathogenic fact or that causes muscle pain and arthralgia, chiefly rheumatic.
(2) A morbid condition marked by intolerance of cold, cold limbs, abdominal distention, diarrhea and edema either caused by attack of damp on the **spleen** resulting in lowered function of this organ (**deficiency of yang**) or due to deficiency of yang of the spleen and the **kidney** with accumulation of damp, e.g., **cold-damp** leukorrhea is characterized by incessant discharge of thin whitish mucus from the vagina, accompanied by lassitude, anorexia, loose bowels, aching in the lumbar regions and cold sensation in the lower abdomen.

collaterals (collateral channels) see **channels and collaterals**

damp (1) An exogenous pathogenic factor that causes syndromes with the following features: chills and persistent fever in spite of perspiration, headache as if the head were tightly bound, lassitude and heaviness sensation in the limbs, anorexia with feeling of stuffiness in the chest and epigastrium, and loose bowels, joint pains and swolling with sensation of heaviness, etc.
(2) Retention of water within the body caused by deficiency of **yang** (vital function of the spleen and the kidney, manifested by anorexia, diarrhea, abdominal distension, oliguria and edema.

damp-heat Heat and damp in combination as a pathogenic factor that causes morbid conditions usually characterized by inflammation with purulent discharges, e.g., acute urinary infection or urolithiasis accompanied by dysuria, passage of turbid urine and hematuria if it attacks the urinary bladder; acute dysentery or diarrhea with mucus and blood in the stools when it invades the large intestine; purulent leukorrhea with a foul smell or pyogenic inflammation of the leg or foot if it pours downward to the lower portion of the body. Furthermore, jaundice in acute cases is also attributed to **damp-heat**.

damp-warm An infectious disease prevalent in summer, marked by prolonged fever, general aching and sensation of heaviness, stuffiness in the chest and distension in the abdomen, and greasy tongue coating. Sometimes it is referred to typhoid or paratyphoid fever.

deficiency The state of being short of what is needed, especially of the functions, energy and essential materials needed for maintaining a healthy life and normal body resistance. Generally speaking, deficiency syndromes include deficiency of qi, of yang, of yin, of vital essence, and of blood.

deficiency-cold see **cold**.

deficiency-fire see **fire**.

deficiency of blood A morbid condition marked by pallor, dizziness, palpitation, insomnia, and numbness of the limbs. It roughly corresponds to anemia, but it may also be found in other diseases (e.g. in neurosis), while a severe anemic patient is usually defficient in both qi and blood.

deficiency of qi A general term for diminshed function of the internal organs and lowered body resistance. Its common features are pallor, lassitude, listlessness, shortness of breath, spontaneous sweating, and weak pulse.

deficiency of yang A general term for lack of physiological energy of life with diminshed functions, marked by pallor, intolerance of cold, cold extremities, loose bowels and feeble pulse.

deficiency of yin A general term for lack of body fluid, vital essence and blood, often resulting in endogenous heat (see internal heat).

deficiency of yin with flaming up of fire (see fire).

deficiency syndrome of the kidney A general term for deficiency of yin and yang of the kidney. The common features are aching and weakness in the loins and knees, seminal omission, impotence, dizziness, tinnitus, forgetfulness, etc. Edema and asthma may also be included in this syndrome.

deficiency syndrome of the liver A general term for deficiency of yin and blood of the liver. The common features are dizziness, headache, irritability, impairment of vision, dryness of the eyes, and menstrual disorders.

diabetes caused by internal heat A morbid condition marked by great thirst, the passage of a large amount of urine, and sometimes excessive eating, comprising diabetes mellitus and diabetes insipidus. According to traditional Chinese medicine, the pathogenesis of diabetes in most instances is deficiency of yin with formation of internal heat. In this book, some of the drugs indicated for diabetes may have a hypoglycemic effect, but the others are used for relieving the symptoms such as polydipsia and polyuria.

dryness (1) An atmospheric pathogenic factor which prevails in dry seasons and impairs the body fluid, resulting in dryness syndrome marked by dryness of the nasal cavity, dry throat, thirst, parched lips, dry cough, and constipation.
(2) An endogenous pathogenic factor caused by impairment of body fluid and also the sydrome thus produced.

dryness-heat Dryness and heat in combination as a pathogenic factor causing sore throat, inflammation of the eyes, dry cough, or hemoptysis.

exogenous affection Morbid condition caused by excessive or untimely atmospheric influences and various infectious factors.

fire (1) Physiological energy of life. This definition is referred to in such expressions as "reinforce the fire" and "invigorate the fire".
(2) An exogenous pathogenic factor that causes morbid conditions marked by acute local inflammation or bleeding accompanied with constitutional manifestations such as aversion to heat, thirst, constipation, reddened tongue with yellowish coating, and forceful rapid pulse.
(3) A morbid condition caused either by hyperactivity of internal organ(s) or by yin deficiency with secondary fire symptoms (also called "deficiency-fire" or "deficiency of yin with flaming up of fire", which is manifested by flushed cheeks, daily recurring fever, heat sensation in the palms and soles, irritability, dryness in the mouth with sore throat, hemoptysis, hyperaphrodisea, etc.).

fire in the liver (liver-fire) A morbid condition of hyperactivity of the liver caused by strong emotional agitations and manifested by headache, dizziness, blood-shot eyes, flushed face, irritability, and hematemesis, hemoptysis or epistaxis. (see fire)

heart A viscus that maintains the blood circulation of the blood and controls the mental activities. Thus, not only the disturbance of blood circulation and irregularity in the sequence of the pulse beat but also various disorders of the higher central nervous system (such as insomnia, forgetfulness, impaired consciousness) are attributed to the dysfunction of the heart.

heat A pathogenic factor that causes morbid conditions characterized by feverishness, flushed face, thirst, craving for cold drink, constipation, reddened tongue with yellowish coating, and rapid pulse. When it causes inflammation with redness, heat and swelling, it is called toxic heat.

heat in blood (1) The late and severest stage of febrile diseases, marked by fever, restlessness, delirium, skin eruption and bleeding (hematemesis, epidstaxis, hematochezia, etc.).
(2) A common cause of bleeding, forcing the blood to flow out of the vessels.

heat in the lung A morbid condition that may be seen in various inflammatory diseases of the respiratory system, marked by cough with thick or yellowish (purulent) sputum, chest pain, dyspnea and even hemoptysis.

internal heat (1) The heat syndrom caused by consumption of yin or body fluid, usually manifested by fever in the afternoon or at night, heat sensation in the chest, palms and soles, night sweating, thirst, constipation, reddened tongue with scanty coating, and thready, rapid pulse.
(2) Invasion of exogenous pathogenic heat into the interior of the body. In this book, internal heat is usually referred to definition (1). It may also be a common cause of diabetes (see diabetes caused by internal heat).

kidney A viscus that stores the essence of life either congenital or acquired (from food) for growth and development, as well as semen for reproduction. It controls urine elimination and water metabolism and helps the lung in accomplishing respiration. It also has direct effect on the condition of the bone and marrow, activities of the brain, hearing of the ears, glossiness of the hair, and sexual power. Thus, in deficiency conditions of the kidney, the common symptoms are aching in the loins where the kidneys are seated, weakness in the knees and legs, impairment of hearing, premature greying of the hair and beard, impotence in male and frigidity in female. In addition, diminished function of the kidney may lead to edema (due to failure in eliminating urine) or dyspnea (due to failure in helping the lung to receive air). Some menstrual disorders, disturbances in mentality, osteopathies, and even looseness of the teeth (the teeth being considered as the odds and ends of the bone) may also be related to deficiency conditions of the kidney.

kidney yang The motive force of the functions of the kidney, including its reproductive function. Deficiency of the kidney yang is often marked by general debility, aversion to cold, cold limbs, listlessness, aching and weakness of the loins and knees, impotence, nocturia, pale tongue with whitish coating.

kidney yin The essential substances in the kidney, serving as the material basis of the kidney functions. Deficiency of the kidney yin is marked by lumbago, lassitude, dizziness, tinnitus, nocturnal emission, thirst, hot sensation in palms and soles, reddened tongue with little or no coating, thready and rapid pulse. Sterility is often attributed to deficiency of the kidney yin.

liver An internal organ that stores blood, smooths the flow of qi (vital energy), controls the function of the tendons, and communicates with the gall-bladder. Thus, dysfunction of the liver may lead to hematemesis or excessive uterine bleeding, stagnation of qi manifested by distending pain in the costal regions, irritability or depression, flaming up of the liver-fire manifested by headache, dizziness, tinnitus and congestion of the eyes, production of wind syndromes of the liver such as vertigo, tremors, spasms or even convulsions, and jaundice if the bile flow is obstructed. Since the essence of the liver and the kidney can reinforce

each other, and deficiency of the one will result in deficiency of the other. many of the drugs replenishing the kidney can replenish the liver at the same time. and vice versa. In addition, the liver has specific relationship with the eyes. and many eye diseases can be treated as liver diseases.

lung A viscus that performs the function of respiration, disseminates qi (vital energy), helps maintain normal water metabolism and controls perspiration, closely relating to the superficial body resistance. Thus, although it is mainly referred to the respiratory system including the upper respiratory tract, its implications are sometimes more extensive.

phlegm (1) Pathologic secretions of the respiratory system, synonymous to sputum if it is ejected from the mouth ("phlegm visible"). Retention of phlegm in the respiratory system is a common pathogenic factor that cause cough and asthma.
(2) A pathologic product of diseased internal organs, especially of the spleen, which in turn may cause various troubles, e.g., nausea and vomiting if it affects the stomach, palpitation, impairment of consciousness or even mania if it invades the heart, scrofula and other nodules under the skin if it accumulates subcutaneously. These troubles are thought to be caused by "phlegm invisible", as they can be effectively treated with the drugs used for the "phlegm visible".
Phlegm can be further classified into cold-phlegm, heat-phlegm, damp-phlegm, wind-phlegm and persistent phlegm. Cold-phlegm is characterized by frothy or watery sputum whitish in colour, accompanied with other cold manifestations such as aversion to cold or chilliness. Heat-phlegm is marked by sticky or purulent sputum accompanied with other heat manifestations such as fever, reddened tongue with yellowish greasy coating and rapid pulse. Dampphlegm is produced by retention of damp due to dysfunction of the spleen, bringing on symptoms such as profuse frothy sputum, epigastric distension, nausea and vomiting. Wind-phlegm usually causes headache, vertigo, numbness of the limbs, stroke or convulsions. Persistent phlegm is often seen in lingering cases of phlegm syndromes such as asthma with repeated attacks; mania and epilepsy are also attributed to persistent phlegm.

phlegm-fire Phlegm and fire in combination as a pathogenic factor that may cause palpitation, headache, vertigo, or mental disorders characterized by an expansive emotional state, hyperirritability, overtalkativeness, and increased motor activity.

phlegm-heat Phlegm and heat in combination as a pathogenic factor invading the respiratory system and causing fever, cough, expectoration of purulent sticky sputum and even dyspnea.

qi The basic element of energy that makes up the human body and supports the vital activities. Since the existence of qi in the human body can only be perceived through its resultant activities of the organs and tissues, it usually implies the functional activity. It circulates in the channels and collaterals. Stagnation of its circulation may result from emotional depression, improper diet, infection and injury, and is often manifested by distension and pain. Deficiency of qi is referred to decreased functional activity, usually manifested by lassitude, listlessness, shortness of breath, spontaneous sweating and weakened pulse. Since each internal organ has its own functional activities, deficiency of qi of different organs may have different manifestations. Drugs to promote the circulation of qi are indicated in the stagnation cases, while drugs to reinforce qi are used for the deficiency cases. To regulate the flow of qi is a general term for treating disorders in the flow of qi.

spleen A viscus that is believed to share with the stomach the function of digesting food, transport and distribute nutrients and water, reinforce the vital energy (qi), and keep the blood flowing within the blood vessels. In most cases, the spleen is referred to the digestive system, taken as the source of nutrients for growth and development, providing the material basis of the acquired constitution. However, dysfunction of the spleen is not confined to digestive disorders; it may also lead to retention of water (see damp) and hemorrhagic disorders such as excessive menstrual discharge and subcutaneous extravasation of blood.

summer-damp A morbid condition caused by summer heat and damp in combination and characterized by fever, fidgetness, feeling of stuffiness in the chest and epigastrium, thirst, diarrhea, and yellowish greasy tongue coating.

summer-heat An exogenous pathogenic factor that causes diseases in summer time, marked by high fever, thirst, profuse perspiration and lassitude.

vital essence (1) The fundamental substance that builds up the physical structure and maintains the body function.
(2) Semen. When this term is used in the context of the kidney, it is referred to both definitions, particularly to the latter.

wind An exogenous pathogenic factor characterized by upward and out-going dispersion, rapid change, and constant movement. Therefore, upper respiratory catarrh with headache and aversion to wind in common cold, morbid conditions with abrupt onset and sudden subsidence such as urticaria, those with wandering symptoms such as migratory pain in rheumatic arthritis, and those with abnormal motion such as convulsion, spasm, tremor, and facial paralysis with deviation of the eyes and the mouth are all believed to be caused by wind. Furthermore, attack of wind on the skin often results in itching.

wind-cold Wind and cold in combination as a pathogenic factor causing chilliness, headache, general aching and a stuffed, running nose.

wind-heat Wind and heat in combination as a pathogenic factor causing marked fever, mild chilliness, cough, thirst, sore throat, headache, or inflammation of the eyes.

wind-phlegm Wind and phlegm in combination as a pathogenic factor causing vertigo, numbness of the limbs, stroke, or epileptic convulsions.

yin and yang Yin-yang is one of the ancient philosophical concepts in China, which holds that anything in the universe is an entity of two aspects-yin and yang, ever opposing and complementing each other. This concept is used in traditional Chinese medicine as a guiding ideology referring to various antitheses in anatomy, physiology, pathology, diagnosis and treatment. In this book, yin and yang are only used in a specific sense, i.e., yin is referred to the material aspect of the body or internal organs, including vital essence, fluid, nutrients, etc., while yang to the functional aspect. For example, yin of the lung means the fluid nourishing and moistening the respiratory system; yang of the kidney implies the physiological energy of life, i.e., fire in its physiological sense, as well as the functions (growth, development, reproduction, metabolism, etc.) produced hereby. In healthy conditions, yin and yang are kept at normal levels and in a relative equilibrium. Breakdown of the balanced equilibrium due to deficiency or excess of either yin or yang will cause diseases. Furthermore, deficiency of the one may lead to excess of the other, e.g., diminished function of the spleen (deficiency of yang) may give rise to retention of water or damp (excess of yin); deficiency of yin of the liver may result in hyperactivity of the

liver or even flamming up of the liver-fire (excess of yang). On the other hand, excess of the one may lead to deficiency of the other, e.g., high fever (excess of yang) consumes the body fluid (yin).